



PATENT
Customer No. 27874
Attorney Docket No. 29794/04001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Randolph M. Howes)	Group Art Unit: 1616
)	
Application No.: 10/050,121)	Examiner: Frank I. Choi
)	
Filed: January 18, 2002)	Attorney Docket No.: 29794/04001
)	
For: Compositions, Methods and)	
Apparatuses for Singlet Oxygen)	
Delivery)	

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

I, Randolph M. Howes, state that I am the named Applicant of the above-identified application, and am the inventor of the subject matter described and claimed therein. Prior to April 29, 1999, I have completed in this country the invention as described and claimed in the above-identified application as evidenced by the following:

1. On March 27 and 28, 1992, I attended a symposium in Photodynamic Therapy at Santa Barbara, California.
2. On the conference materials that were distributed for the conference I took notes on my ideas for methods of delivering singlet oxygen (" $^1\text{O}_2^*$ ") to a target site.
3. On March 29, 1992, I recorded the following notes:

“RMH

3/29/92

– one could also use $^1\text{O}_2^*$ in an irrigating system for wound cavities such as emphyemas or peritonitis or a wound surface – this would have both bacteriocidal & tumoricidal activity” (Exhibit 1.)

“– an added advantage of injectable $^1\text{O}_2^*$ is that there is literally no limit to depth of treatment such as seen with PDT in which the light can penetrate only to 5 mm or where diffusion techniques have to be employed” (Exhibit 2.)

“– one could use endoscopes to place the treating $^1\text{O}_2^*$ virtually anywhere in the body utilizing the injection technique” (Exhibit 2.)

4. In September 1993, I tested the inventive concept on myself.

5. On September 14, 1993, I recorded the following notes as I tested the invention on myself:

“9/14/93 10PM RMH – lesion 0.5 cm dia

– will inj. keratosis on right shoulder with H_2O_2 & NaOCl – 0.1 cc each with 25 gauge needle & 1 cc tuberculin syringe

– will use 1% xylocaine with 1:100,000 epi

10:15 PM – inj. with xylocaine

10:25 PM – inj. with NaOCl – painful

“ “ H_2O_2 – turned white

11:30 – still painful but turning black

12:00 MN – looks like early scab” (Exhibit 3.)

6. On September 15, 1993, I recorded the following notes based on observations of the September 14, 1993-injection site:

- “9/15/03¹ – injected lesion now black with eschar
- looks like it killed it
- will try again
- will wait longer for local anesth.” (Exhibit 3.)

7. On September 21, 1993, I recorded the following notes based on observations of the September 14, 1993-injection site:

- “9/21/02² – still not sloughed off but lesion is definitely dead” (Exhibit 3.)

8. On March 15, 1996, I repeated the test of the invention on myself, this time reversing the order of the reactant injections.

9. On March 15, 1996, I recorded the following notes as I repeated the invention on myself:

- “RMH – 3/15/96 will repeat injection but will use dermal nevus or keratosis.
- 1% xylocaine 1:100,000 epi
- nevus on Left forearm <0.3 cm dia
- inj. 0.1 cc H₂O₂ first then NaOCl
- can’t inj. both together – needles too awkward
- seemed to work better with NaOCl first, then follow with H₂O₂” (Exhibit 4.)

10. On March 16, 1996, I recorded the following notes relating to the injection site:

¹ Note that I incorrectly recorded the date as “9/15/03”. In fact, I recorded the notes on September 15, 1993.

² Note that I incorrectly recorded the date as “9/21/02”. In fact, I recorded the notes on September 21, 1993.

Application No. 10/051,121
Attorney Docket No. 29794/04001
Declaration Under 37 C.F.R. § 1.131

“3/16/96 11AM – did do as well as with H₂O₂ first but did turn black, like with PDT” (Exhibit 4.)

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Date: _____

Dr. Randolph M. Howes

Application No. 10/051,121

Attorney Docket No. 29794/04001

Declaration Under 37 C.F.R. § 1.131

"RMH

3/29/92

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Application No. 10/051,121

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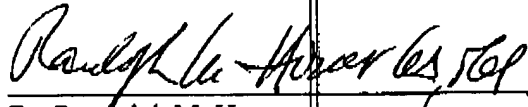
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Application No. 10/051,121
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"3/16/96 11AM - did do as well as with H₂O₂ first but did turn black, like with
PDT" (Exhibit 4.)

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Date: 11/21/04


Dr. Randolph M. Howes

rest

✓ use
hole

EXHIBIT

1

7/24/92

- one could also use O_2 in an irrigating system for wound cavities such as eardrums or peritonitis on a wound surface - this would have both bactericidal & fungicidal activity.

REDACTED

REDACTED

REDACTED

REDACTED

BEST AVAILABLE COPY

3/29/92
— an added advantage of injectable O_2 is
that there is literally no limit to depth
of treatment such as seen with PDT, in
which the light can penetrate only to 5 mm,
or where diffusion techniques have to be employed

REDACTED

REDACTED

REDACTED

8:39 PM 3/29/92 - in flight
— one would use endoscopes to place the breathing
 O_2 virtually anywhere in the body utilizing the
injection technique

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REDACTED



REDACTED

REDACTED

9/14/93 0800 hrs - heard 0.8 can die
 - with ag. Resistor in @ shoulder & throat
 Made - 0.8 can work & 25 g. would be
 Ice tedaculis syringe
 - with urea 12.5 g. can work & 15,000,000 g. d
 10⁰⁰ hrs - ag. & syringe
 10²⁰ hrs - ag. & 1000 - painful
 " " 10⁴⁰ - found white
 11³⁰ - still painful but trying block
 1200 hrs - looks like the early seal

9/15/93 - injected 1000 now black & color
 - looks like the 1000 is dead
 - with 1000 ag. & syringe
 - will wait 1000 for local anesthetic.

9/21/93 - still not slogged off but
 lower is definitely dead

BEST AVAILABLE COPY

REDACTED

but - 3/15/96 with repeat injection but could see
dental news or computer. (Copy sent 1:00 am 3/16/96)

Never on forearm < 0.3 in dia

- in or a bit further than Nucle
- can't dig both together - needles to work
- seemed to work better w Nucle first

The follow's then

3/14/96 11pm - did do as well as 5th first
but did turn black, like a PDT